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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,806	10/03/2008	Daniel Harari	HARARI 1	7157

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BROWDY AND NEIMARK, P.L.L.C.
624 NINTH STREET, NW
SUITE 300
WASHINGTON, DC 20001-5303

EXAMINER	
XIE, XIAOZHEN	

ART UNIT	PAPER NUMBER
1646	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,806	HARARI, DANIEL	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I. Claims 1-14 and 32 are drawn to a polypeptide, and a pharmaceutical composition thereof, comprising **one** splice variant of an ErbB ligand, wherein **one** specific SEQ ID NO is identified from SEQ ID NOs: 74-84, 93, 95-104 and 109-121.

Group II. Claims 15-26, 28-31 and 33 and are drawn to a polynucleotide, a vector and a host cell comprising same, and a pharmaceutical composition thereof, wherein the polynucleotide encoding **one** splice variant of an ErbB ligand, and **one** specific SEQ ID NO is identified for the splice variant from SEQ ID NOs: 128-139 and 149-182.

Group III. Claims 27 and 34 is drawn to an antisense oligonucleotide, and a pharmaceutical composition thereof, capable of specifically inhibiting the expression of **one** splice variant of an ErbB ligand, wherein **one** specific SEQ ID NO is identified for the splice variant from SEQ ID NOs: 74-84, 93, 95-104 and 109-121.

Group IV. Claims 35 and 36 are drawn to a method of treating a disease or disorder related to an ErbB receptor comprising administering a polypeptide comprising a splice variant of an ErbB ligand.

Group V. Claims 37 and 38 are drawn to a method of treating a disease related to pathological activity of an ErbB receptor comprising administering a polynucleotide encoding **one** splice variant of an ErbB ligand, wherein **one** specific SEQ ID NO is identified for the polynucleotide from SEQ ID NOs: 128-139 and 149-182.

Group VI. Claims 39 and 40 are drawn to a method for selectively enhancing or promoting the proliferation or differentiation of stem cells expressing ErbB receptors comprising exposing the stem cells to **one** ErbB ligand splice variant, wherein **one** specific SEQ ID NO is identified for the splice variant from SEQ ID NOs: 74-84, 93, 95-104 and 109-121.

The inventions listed as I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

According to PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art. The inventions listed as Groups I-VI do not relate to a single general inventive concept because they lack the same or corresponding technical feature. The technical feature of claim 1 in Group I is a polypeptide comprising a splice variant of an ErbB ligand encoded by differential exon usage comprising a truncated EGF domain devoid of the C-loop of the

EGF domain, which is anticipated by Wen et al. (Mol. Cell. Biol., 1994, Vol. 14(3):1909-1919). Wen et al. teach isoforms of Neu differentiation factors (NDFs) which is a ligand for a receptor tyrosine kinase encoded by *neu* proto-oncogene (also known as *HER-2* or *c-erbB-2*). Wen et al. teach an NDF isoform which comprises a truncated EGF domain devoid of the C-loop of the EGF domain (pp. 1912, Fig. 1). Wen et al. teach the limitations of claim 1, and therefore the technical feature of Group I lacks novelty or inventive step and does not make a contribution over the prior art.

Since the 1st claimed invention has no special technical feature, it cannot share a special technical feature with the other claimed inventions.

Further, the polypeptides of Group I, the polynucleotides of Group II, and the antisense oligonucleotides of Group III, each of the groups represents multiple distinct products which have distinctly different structures as represented by their different SEQ ID NOs. Thus, each of the products is drawn to a distinct invention, and the PCT rules do not provide for the examination of multiple products, multiple methods of making one product, or multiple methods of using one product in one application.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie, Ph.D. whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Xiaozhen Xie/
Xiaozhen Xie, Ph.D.
October 29, 2009